



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/593,383

09/19/2006

Elliott P. Dawson

16304-1US

7404

23676 7590 08/10/2009  
SHELDON MAK ROSE & ANDERSON PC  
100 Corson Street  
Third Floor  
PASADENA, CA 91103-3842

EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

08/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,383	<b>Applicant(s)</b> DAWSON ET AL.	
	<b>Examiner</b> Jane Zara	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 33-86 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The restriction requirement mailed 6-24-09 is **hereby VACATED** and a new one is set forth below.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 371.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 34-86, drawn to methods of isolating a microRNA of interest from a sample comprising a single or plurality of microRNAs of interest.

Applicant is required under 35 U.S.C. 121 to elect a **single disclosed construct** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Thus, Applicants must elect a **single** nucleic acid construct, showing which of the sequences or subcomponents are identical or different for that molecule, and which are necessary to define said construct, compound or composition. Claim 33 link(s) the various inventions described above. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 33. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or

Art Unit: 1635

including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

The various inventions encompassed by Group I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 34-86 are drawn to a methods, processes, compositions comprising or utilizing a plurality of nucleic acid constructs, optionally comprising first, second, third, etc. adapter segment sequences, microRNA binding segments, and first, second, etc. linkers. Therefore, this application does not comply with the requirements for unity of invention (Rules 13.1, 13.2 and 13.3) for the following reasons:

According to the guidelines in section (f)(i)(a) of annex B of the PCT Administrative Instruction, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush group are of similar nature. The instant methods and compositions comprising or utilizing a plurality of components within a single construct for capturing or isolating microRNA set forth in and/or encompassed by claims 1-86 are considered to be each separate inventions for the following reasons:

The different sequences, nucleic acids, targets, structures utilized by the different processes and methods do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. In the instant case, the various constructs

Art Unit: 1635

optionally comprising different or identical components or subcomponents (e.g., first, second, third... adapter segment sequences, combined with different or identical microRNA binding segments, and different or identical linkers, all of which may be identical with, or different from each other) encompass a myriad of structurally and functionally distinct compounds. Each construct is independent or distinct because the oligomeric compounds, defined by the various combinations recited in claims 33-86, have different structures and, therefore, different chemical properties and biological effects. For example, the different constructs may differ with regard to solubility, binding properties, higher order structure, and nuclease stability, all of which are expected to contribute to their mode of action in different biological or biochemical environments. The different constructs would also differ in their reactivity and the starting materials from which they are made. It is also possible that the method and utility of each would differ according to the best binding conditions required for each construct and testing environment, and the particular applications each is suited for because each recites several different possible components that may be placed on the same or other claimed compound or construct.

Applicant is required under 37 U.S.C. 1.475 to elect a single disclosed nucleic acid construct for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Thus, Applicants must elect a **single** nucleic acid construct, showing which sequences or subcomponents that are identical or different for that molecule, and that are necessary to define said construct, compound or composition.

Art Unit: 1635

Each of the constructs comprise sequences that are different for a particular target molecule, microRNA, capture probe, linker and microRNA binding site, and so each is structurally and chemically and biologically different and distinct, and the different molecules and biological structures and entities, and the different methods and screening processes target different molecules to varying degrees, or measure different phenotypes, biochemical and/or biological effects. Each member of the class cannot be substituted one for the other with the expectation that the same intended result would be achieved or measured.

Further, the different Groups of compounds and target molecules and processing constructs, and the different methods do not meet the criteria of (B)(1) as they do not share, one with another, a common core structure. Accordingly, unity of invention between the myriad of possible combinations is lacking and each nucleic acid construct is considered to constitute a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Art Unit: 1635

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**Jane Zara**  
**8-6-09**

/Jane Zara/

Primary Examiner, Art Unit 1635